

Krain W. K.



PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES	ATTORNEY'S DOCKET NUMBER
DESIGNATED/ELECTED OFFICE (DO/EO/US)	2343-181-64 NATL
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
	10/541.246
INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PCT/US04/00740 14 January 2004	PRIORITY DATE CLAIMED
PCT/US04/00740 14 January 2004 TITLE OF INVENTION METHODS OF PREPARATION OF LIVE ATTENU	14 January 2003 ATED BACTERIAL VACCINES BY
ALTERATION OF DNA ADENINE METHYLASE (DAM) ACTIVITY	
APPLICANT(S) FOR DO/EO/US	
Mark L. LAWRENCE, et al.	
Applicant herewith submits to the United States Designated/Elected Office (DO/EC	D/US) the following items and other information:
1. This is a FIRST submission of items concerning a submission under 35 U.S.C. 37	1.
2. X This is a SECOND or SUBSEQUENT submission of items concerning a submission	n under 35 U.S.C. 371.
3. This is an express request to begin national examination procedures (35 U.S.C. 37 (5), (6), (9) and (21) indicated below.	(1(f)). The submission must include items
4. The US has been elected (Article 31).	
5. A copy of the International Application as filed (35 U.S.C. 371(c)(2))	
a. is attached hereto (required only if not communicated by the Internatio	nal Bureau).
b. has been communicated by the International Bureau.	0.6 (0.040)
c. is not required, as the application was filed in the United States Received	
6. An English language translation of the International Application as filed (35 U.S.	C. 3/1(c)(2)).
 a. is attached hereto. b. has been previously submitted under 35 U.S.C. 154(d)(4). 	
7. Amendments to the claims of the International Application under PCT Article 19	(35 U.S.C. 371(c)(3))
a. are attached hereto (required only if not communicated by the Interna	
b. have been communicated by the International Bureau.	,
c. have not been made; however, the time limit for making such amend	ments has NOT expired.
d. have not been made and will not be made.	
8. An English language translation of the amendments to the claims under PCT A	rticle 19 (35 U.S.C. 371(c)(3)).
9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).	,
10. An English language translation of the annexes of the International Preliminary Article 36 (35 U.S.C. 371(c)(5)).	Examination Report under PCT
Items 11 to 20 below concern document(s) or information included:	
11. X An Information Disclosure Statement under 37 CFR 1.97 and 1.98.	
12. An assignment document for recording. A separate cover sheet in compliance w	rith 37 CFR 3.28 and 3.31 is included.
13. A preliminary amendment.	
14. An Application Data Sheet under 37 CFR 1.76.	
15. A substitute specification.	. •
16. A power of attorney and/or change of address letter.	
17. A computer-readable form of the sequence listing in accordance with PCT Rule	
18. A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. A second copy of the English language translation of the international application	n under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S.

Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT,

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Page 1 of 3

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MN/

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U.S. APPLICAT	ION NO. (if known,	(if known, see 37 CFR 1.5) INTERNATIONAL APPLICATION NO.		PLICATION NO.	ATTORNEY'S DOCKET NUMBER		
10/541.2	7/541,246 PCT/US04/00740			2343-181-64 NATL			
ID		neet, Form	PTO-1449, Cited	d Documents	(51), Statemen	t of	
The follo	wing fees have b	een submitted	·		CALCULATIONS	PTO USE ONLY	
	•			\$300	\$		
22.	ination fee (37 CF	R 1.492(c))					
by IPĖA/l	JS indicates all cla	aims satisfy provis	national preliminary examina sions of PCT Article 33(1)-(4)	\$0	\$		
If the written opini IPEA/US Search fee (37 Cl Internatio International Sear	indicates all claim FR 1.445(a)(2)) ha mal Searching Au rch Report prepan communicated to	or the Internationals satisfy provisionals been paid on the thorityed by an ISA other the US by the IB	al preliminary examination rens of PCT Article 33(1)-(4)ne international application to	\$0 the USPTO as an\$100 o the Office or\$400	\$		
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Additional fee sequence electronic	e for specification e listing in complia c medium) (37 CF	and drawings filed ince with 37 CFR R 1.492(j)).	d in paper over 100 sheets (e 1.821(c) or (e) or computer p of paper or fraction thereof.	excluding program listing in an			
Total Sheets	Extra Sheets		additional 50 or fraction up to a whole number)	RATE			
- 100 =	/50 =			× \$250	\$		
			h fee, examination fee, or the e (37 CFR 1.492(h)).	e oath or declaration	\$		
CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$		
Total claims		- 20 =		x \$50	\$		
Independent clair	ns	- 3 =		× \$200	\$		
MULTIPLE DEPE	NDENT CLAIM(S	6) (if applicable)		+ \$360	\$		
			TOTAL OF ABOVE	CALCULATIONS =	\$		
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.							
	*			SUBTOTAL =	\$		
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).			\$				
TOTAL NATIONAL FEE =			\$				
• -	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +			\$			
			TOTAL	FEES ENCLOSED =	\$		
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a. A check in the amount of \$	to cover the above fees is enclosed.
b. Please charge my Deposit Account No i A duplicate copy of this sheet is enclosed.	n the amount of \$ to cover the above fees.
c. The Commissioner is hereby authorized to charge any a Account No. $\underline{50-1442}$ A duplicate copy of this she	additional fees which may be required, or credit any overpayment to Deposit et is enclosed.
d. Fees are to be charged to a credit card. WARNING: Info be included on this form. Provide credit card information	ormation on this form may become public. Credit card information should not ion and authorization on PTO-2038.
NOTE: Where an appropriate time limit under 37 CFR 1.495 h and granted to restore the International Application to pendic	nas not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed ng status.
SEND ALL CORRESPONDENCE TO: Patent Group DLA Piper Rudnick Gray Cary US LLF 1200 Nineteenth Street, N.W. Washington, D.C. 20036-2412	SIGNATURE Ping Wang NAME 48,328 REGISTRATION NUMBER

Docket No.: 2343-181-64 NATL

IN THE UN D STATES PATENT AND TRADEMARK () ICE

IN RE APPLICATION: Mark L. LAWRENCE, et al.

GROUP ART UNIT:

SERIAL NUMBER: 10/541,246

EXAMINER:

FILED: July 1, 2005

FOR: METHODS

METHODS OF PREPARATION OF LIVE ATTENUATED BACTERIAL VACCINES BY ALTERATION OF DNA

ADENINE METHYLASE (DAM) ACTIVITY IN THOSE BACTERIA

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents PO BOX 1450 ALEXANDRIA, VA 22313-1450

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are either statements of relevancy or any readily available full or partial English translations of any non-English-language documents.

RELATED CASES

Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

- each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.
- no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

- without fee and within three months of the filing date of the application.
- without fee and within three months of the date of entry of the U.S. national stage.
- without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
- □ without fee and with the appropriate certification above.
- without fee and with a new CPA application.
- without fee and with a Request for Continued Examination.
- with fee and before the mailing date of any Final Office Action, Notice of Allowance or an action that otherwise closes prosecution (to the knowledge of the undersigned).
- with fee, appropriate certification above, and before payment of the Issue Fee.

DEPOSIT ACCOUNT

Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

Respectfully submitted,

DLA PIPER RUDNICK GRAY CARY US LLP

James M. Heintz

Registration No. 41,828

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Telephone No. (202) 861-3900
Ping Wang, M.D.
Facsimile No. (202) 2013-2018 FERENCES CONSIDER Guster to No. (202) 861-3900

01/05

DOCKET NO. 2343-181-64 NATL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Mark L. LAWRENCE

ART UNIT:

SERIAL NO.: 10/541,246

EXAMINER:

FILING DATE: January 14, 2004

FOR:

METHODS OF PREPARATION OF LIVE ATTENUATED BACTERIAL

VACCINES BY ALTERATION OF DNA ADENINE METHYLASE (DAM)

ACTIVITY IN THOSE BACTERIA

STATEMENT OF RELEVANCY

ASSISTANT COMMISSIONER FOR PATENTS PO BOX 1450 ALEXANDRIA, VA 22313-1450

SIR:

This Statement of Relevancy is herewith submitted with the concurrently filed Information Disclosure Statement. The below cited German language articles are submitted for consideration in the examination of the above-identified application in which an English language translation of the articles could not be located.

1. Geschwend, et al., Berl. Munch Tierarztl Wschr, Vol. 110, (1997).

The above cited article briefly describes that Pasteurella multocida and Pasteurella haemolytica produce specific proteins in the outer membrane under iron-depleted conditions. Pasteurella multocida serovar A expresses these proteins of molecular masses of 76 and 96 kDa as determined by electrophoresis. The analogous serovar D produces a further iron-regulated protein of 85 kDa. The Pasteurella haemolytica strains of serovar A1, A6 and T contain iron-regulated outer membrane proteins of molecular masses of 71, 77 and 100 kDa. These proteins possess binding positions for iron ions. This article also briefly describes that both *Pasteurella multocida* and *Pasteurella haemolytica* strains utilize iron from porcine and bovine transferrin, but not from haemin and haemoglobin.

Consideration of the above cited references with all Information Disclosure Materials concurrently filed is respectfully requested.

Respectfully submitted,

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James M Heintz

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DOCKET NO.: 2343-181-64 NATL

LIST OF RELATED CASES

Docket Number	Serial or Patent Number	Filing or Issue Date	Status or Patentee
2343-013-27	5,403,863	04-04-06	Granted
2343-179-27	10/767,441	01-30-04	Pending
2343-181-64 NATL	10/541,246	07-01-05	Pending
2343-203 NATL	11/372,187	03-10-06	Pending

The cases listed on this Notice of Related Cases include cases which may contain information that is material to patentability. The listing of a case on this Notice should not be taken as an indication or admission that any information contained therein is material. Prior art for each case listed on this Notice may have been cited. The files corresponding to the listed cases, which are available to the Examiner, may not have not been examined to ascertain the materiality of any prior art therein. Accordingly, the Examiner is requested to review the file for each case listed on this Notice in order to assess the materiality of such prior art.

^{*}Present application; listed for information.

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				Mark L. Lawrence, et al.				· .
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	AA	5,403,863	04-04-95	Mark L. Lawrence, et al.				
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			Mark L. LAWRENCE, et al.		
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	ВВ	Collier, "Significance of Bacte 1968.	ria in Bovine Respiratory Disease", A	a.V.M.A., Vol. 153, No. 12, pp. 1645-1651,	
	ВС	Schiefer, et al., "Correlation of Pathol., Vol. 15, pp. 313-321,		ndings in Bovine Fibrinous Pneumonia", Vet.	
	BD	Purdy, et al., "Serotyping and Enzyme Characterization of <i>Pasteurella haemolytica</i> and <i>Pasteurella multocida</i> Isolates Recovered from Pneumonic Lungs of Stressed Feeder Calves", Current Microbiology, Vol. 34, pp. 244-249, 1997.			
	BE	Allen, et al., "The Microbial Flora of the Respiratory Tract in Feedlot Calves: Associations between Nasopharyngeal and Bronchoalveolar Lavage Cultures", Can. J. Vet. Res., Vol. 55, pp. 341-346, 1991.			
	BF	Singer, et al., "Assessment of spatial and temporal clustering of ampicillin- and tetracycline-resistant strains of <i>Pasteurella multocida</i> and <i>P haemolytica</i> isolated from cattle in California", JAVMA, Vol. 212, No. 7, pp. 1001 1005, 1998.			
	BG	Gourlay, et al., "Experimental 1989.	Pasteurella multocida pneumonia in	calves", Res. Vet. Sci., Vol. 47, pp. 185-189,	
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	BI		and pathologic characteristics of resp VMA, Vol. 208, No. 12, pp. 2035-204	iratory tract disease in dairy heifers during the 2, 1996.	
	BJ	Boyce, et al., "The Capsule Is a Virulence Determinant in the Pathogenesis of <i>Pasteurella multocida</i> M1404 (B:2)", Infection and Immunity, Vol. 68, No. 6, pp. 3463-3468, 2000.			
	ВК	Rimler, et al., "Lipopolysaccharides of the Heddleston serotypes of <i>Pasteurella multocida</i> ", Am. J. Vet. Res., Vol. 45, No. 4, pp. 759-763, 1984.			
	BL	Brogden, et al., "Incubation of <i>Pasteurella haemolytica</i> and <i>Pasteurella multocida</i> lipopolysaccharide with sheelung surfactant", Am. J. Vet. Res., Vol. 47, No. 4, pp. 727-729, 1986.			
	ВМ		ination of rabbits with Pasteurella mol. 62, No. 5, pp. 697-703, 2001.	ultocida A:3 outer membranes that express iron	
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in conformance and not considered. Include copy of this form with next communication to Applicant.

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(Modified)		TENT AND TRADEMARK FICE	2343-181-64 NATL	10/54	1,246
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			Mark L. LAWRENCE, et al.		
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(Use	Several	Sheets if Necessary)	July 1, 2005		
	-	OTHER REFERENCES	(Including Author, Title, Date, Pertino	ent Pages, Etc.)	
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	во	Negrete-Abascal, et al., "Secret 64-67, 1999.	ion of Proteases from Pasteurella mul	tocida Isolates", Cur	rr. Micribiol., Vol. 38, pp.
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	ВQ	White, et al., "Extracellular Neuraminidase Production by a <i>Pasteurella multocida</i> A:3 Strain Associated with Bovine Pneumonia", Infection and Immunity, Vol. 63, No. 5, pp. 1703-1709, 1995.			rain Associated with
	BR	Galdiero, et al., "Effects of the major <i>Pasteurella multocida</i> porin on bovine neutrophils", AJVR, Vol. 59, No. 10, pp. 1270-1274, 1998.			
	BS		Fuller, et al., "Identification of <i>Pasteurella multocida</i> virulence genes in a septicemic mouse model using signature-tagged mutagenesis", Microb. Pathog., Vol. 29, pp. 25-38, 2000.		
	вт	May, et al., "Complete genomic No. 6, pp. 3460-3465, 2001.	May, et al., "Complete genomic sequence of <i>Pasteurella multocida</i> , Pm70", Proc. Natl. Acad. Sci. USA, Vol. 98, No. 6, pp. 3460-3465, 2001.		
	BU	Blyn, et al., "Regulation of pap states", The EMBO J., Vol. 9,	pilin phase variation by a mechanism No. 12, pp. 4045-4054, 1990.	involving differentia	al Dam methylation
	BV	Braaten, et al., "Methylation Pa Variation in E. coli", Cell, Vol.	atterns in <i>pap</i> Regulatory DNA Contro 76, pp. 577-588, 1994.	l Pyelonephritis-Ass	ociated Pili Phase
	AW		van der Woude, et al., "Leucine-responsive regulatory protein and deoxyadenosine methylase control the phase variation and expression of the <i>sfa</i> and <i>daa</i> pili operons in <i>Escherichida coli</i> ", Mol. Microbiol., Vol. 11, No. 4, pp 605-618, 1994.		
	BX	Henderson, et al., "The Major Phase-Variable Outer Membrane Protein of <i>Escherichia coli</i> Structurally Resembles the Immunoglobulin A1 Protease Class of Exported Protein and Is Regulated by a Novel Mechanism Involving Dan and OxyR", J. of Bacteriol., Vol. 181, No. 7, pp. 2132-2141, 1999.			
	BY	Heithoff, et al., "An Essential Role for DNA Adenine Methylation in Bacterial Virulence", Science, Vol. 284, pp. 967-970, 1999.			
	BZ		ethylase Is Essential for Viability and I cholerae", Infect. and Immun., Vol. 6		
EXAMINER				DATE CONSIDER	RED
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Form PTO 1449	1449 U.S. DEPARTMENT OF COMMERCE		DOCKET NO.	SERIAL NO.	
(Modified) PATENT AND TRADEMARK OFFICE		ENT AND TRADEMARK	2343-181-64 NATL	10/541,246	
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		Sheets if Necessary)	July 1, 2005		
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	CA	Fleischmann, et al., "Whole-Ge Vol. 269, pp. 496-512, 1995.	enome Random Sequencing and Assembly of Haen	nophilus influenza Rd", Science,	
	СВ	Palmer, et al., "The <i>dam</i> and <i>da</i> 12, 1994.	cm strains of Escherichida coli - a review", Gene, V	Vol. 143, Supplement 37, pp. 1-	
	CC	Ausubel, et al., "Preparation of New York: John Wiley and Son	Genomic DNA from Bacteria", Current Protocols ns, 1994.	in Molecular Biology, New York,	
	CD	Altschul, et al., "Gapped BLAS Acids Research, Vol. 25, No. 1	ST and PSI-BLAST: a new generation of protein da 7, pp. 3389-3402, 1997.	atabase search programs", Nucleic	
	CE	Thompson, et al., "CLUSTAL W: improving the sensitivity of progressive multiple sequence alignment through sequence weighting, position-specific gap penalties and weight matrix choice", Nucleic Acids Res., Vol. 22, No. 22, pp. 4673-4680, 1994.			
	CF	Reese, et al., "Large Scale Sequencing Specific Neural Networks for Promoter and Splice Site Recognition", Biocomputing: Proceedings of 1996 Pacific Symposium, pp. 737-739, 1996.			
	CG	Willson, et al., "Characterization of a Multiple Antibiotic Resistance Plasmid from <i>Haemophilus ducreyi</i> ", Antimicrob. Agents Chemother., Vol. 33, No. 9, pp. 1627-1630, 1989.			
	СН	Jablonski, et al., "Conditions for transformation of <i>Pasteurella multocida</i> by electroporation", Micro. Pathog., Vol. 12, pp. 63-68, 1992.			
	CI	Jonczyk, et al., "The <i>Escherich</i> Vol. 217, pp. 85-96, 1989.	Jonczyk, et al., "The Escherichia coli dam gene is expressed as a distal gene of a new operon", Mol. Gen. Genet.,		
	СЈ	Herman, et al., "Escherichia coli K-12 Clones That Overproduce dam Methylase Are Hypermutable", J. Bacteriol., Vol. 145, pp. 644-646, 1981.			
	CK	Glickman, et al., "Induced Mutagenesis in dam - Mutants of Escherichia coli: A Role for 6-Methyladenine Residues in Mutation Avoidance", Mol. Gen. Genet., Vol. 163, pp. 307-312, 1978.			
	CL	Bale, et al., "Characterization of DNA Adenine Methylation Mutants of <i>Escherichia coli</i> K12", Mutant. Res., Vol. 59, pp. 157-165, 1979.			
	СМ	Marinus, et al., "Biological Fu Biol., Vol. 85, pp. 309-322, 19	nctions for 6-Methyladenine Residues in the DNA 174.	of <i>Escherichia coli</i> K12", J. Mol.	
	CN		uence of the dam Methylase of Escherichia coli K n., Vol. 254, No. 4, pp. 1408-1413, 1979.	12 and Mode of Cleavage of Dpn	
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			er or not citation is in conformance with MPEP 60	9; draw line through citation if not	

Form PTO 1449		. DEPARTMENT OF MMERCE	DOCKET NO.	SERIAL NO.	
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			APPLICANT		
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	со	Modrich, "Methyl-directed DN	NA Mismatch Correction", J. Biol. Ch	em., Vol. 264, No. 12, pp. 6597-6600, 1989.	
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	CQ	Heithoff, et al., "Salmonella DNA Adenine Methylase Mutants Confer Cross-Protective Immunity", Infect. and Immun., Vol. 69, No. 11, pp. 6725-6730, 2001.			
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EXAMINER /Albert M Navarro/				DATE CONSIDERED 01/27/2009	

in conformance and not considered. Include copy of this form with next communication to Applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MN/